(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 618 861 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
01.12.1999 Bulletin 1999/48

(21) Application number: **92920127.5**

(22) Date of filing: **04.09.1992**

(51) Int. Cl.[6]: **B29C 65/16**, A61M 25/00

(86) International application number:
PCT/US92/07340

(87) International publication number:
WO 93/10961 (10.06.1993 Gazette 1993/14)

(54) LASER BONDING OF ANGIOPLASTY BALLOON CATHETERS

LASERSCHWEISSEN VON ANGIOPLASTIE BALLONKATHETERN

LIAISON LASER DE CATHETERS A BALLONNET UTILISES EN ANGIOPLASTIE

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **29.11.1991 US 800201**

(43) Date of publication of application:
12.10.1994 Bulletin 1994/41

(60) Divisional application:
98200064.8 / 0 839 634

(73) Proprietor: **SCHNEIDER (USA) INC.**
Plymouth, Minnesota 55442 (US)

(72) Inventor: **FORMAN, Michael, R.**
St. Paul, MN 55116 (US)

(74) Representative:
Hermann, Gerhard, Dr. et al
Vossius & Partner,
Postfach 86 07 67
81634 München (DE)

(56) References cited:

EP-A- 0 087 403	EP-A- 0 131 918
DE-A- 1 479 239	JP-A- 61 103 688
US-A- 3 528 869	US-A- 3 769 117
US-A- 3 953 706	US-A- 4 251 305
US-A- 4 550 238	US-A- 4 733 047

- **PATENT ABSTRACTS OF JAPAN vol. 8, no. 2 (M-266)(1439) 7 January 1984 & JP,A,58 166 168 (TOKYO SHIBAURA DENKI) 1 October 1983**

EP 0 618 861 B1

Printed by Xerox (UK) Business Services
2.16.7/3.6

Description

Background of the Invention

[0001] The present invention relates to dilatation balloon catheters employed in percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) procedures, and more particularly to the means for forming fluid tight seals between these catheters and their associated dilatation balloons.

[0002] Balloon catheters are well known for their utility in treating certain types of obstructions or occlusions in blood vessels, such as plaque build up. Angioplasty catheterization typically involves aligning a balloon catheter within the vessel to position its dilatation balloon at or along the obstruction. Then, fluid under pressure is supplied to the balloon through a balloon inflation lumen in the catheter, expanding the balloon against the obstruction.

[0003] In the manufacture of balloon catheters, it is essential that the bonds between the catheter and the surrounding dilatation balloon material be consistent, fluid tight and of sufficient strength to withstand the fluid pressures involved in balloon dilatation. Typically the dilatation balloon is mounted along the distal end region of the catheter and surrounds the catheter. A main body portion or medial region of the balloon has a diameter substantially larger than that of the catheter, with proximal and distal shafts or neck regions of the balloon having inner diameters substantially equal to the outer diameter of the catheter. Proximal and distal tapered portions, or cones, join the medial region to the proximal and distal shafts, respectively, with each cone diverging in the direction toward the medial region. The bonds between the balloon and catheter are formed along the proximal and distal shafts.

[0004] One known bonding approach for heat fusible materials involves the resistance heating of copper jaws, while the jaws press the respective balloon shafts onto and against the catheter. One result of the deformation of the balloon and catheter material is the formation of small, random channels at the balloon/catheter interface, giving rise to variations in the strength of different bonds. To compensate for this variance, bonds are given a sufficient length to provide the requisite burst strength, typically axial dimensions in the range of about (0.070-0.150 inches) 0.178-0.381 cm. The copper jaws heat the balloon shafts and catheter primarily by conduction but also by radiation. The heat causes crystallization and stiffening of the balloon and catheter material, not only at the bond site, but also in both directions axially of the bond, due to heat conduction through the balloon and the catheter, and heat radiation from the jaws.

[0005] Several disadvantages arise from crystallization and stiffening at and around the bond. Stiffness along the catheter distal tip, distal balloon shaft and proximal bond area interferes with movement of the catheter along narrow and convoluted arteries, and increase the risk of trauma to the intima. To the extent that crystallization extends to the balloon tapered cones, catheter maneuverability is further reduced, and cone stiffness prevents a complete evacuation of radiopaque dye or other fluid from the balloon following dilatation.

[0006] Crystallization at the cones can be reduced or avoided by sufficient axial spacing between each of the balloon cones and its associated bond. However, this approach further increases the minimum required length of the distal balloon shaft. More particularly, it has been found that a gap of at least .030 inches (0.0762 cm) between the bond and balloon cone is required, to satisfactorily reduce crystallization in the cone.

[0007] Other approaches to bonding avoid the use of copper jaws. For example, U.S. Patent No. 4,251,305 (Becker et al) discloses a non-contact method for heat sealing a balloon onto a catheter. A length of thin tubing is slid over an elongated shaft of the catheter. Shrink tubing is installed over the thin walled tubing at its ends, and overlapping the shaft, and partially shrunk. Then, lamps provide further radiant energy to form gradually tapering thermoplastic joints that bond the tubing and shaft. The device employed for bonding utilizes three lamps that emit energy along the visible and infrared spectra. Each lamp is situated near an elliptical reflector, at one of the foci of the ellipse. The bond or treatment area is near the other focus. While this approach avoids the problems arising from mechanical squeezing from the copper jaws, the undesirable axial conductive heat transfer remains a problem.

[0008] Adhesives can be employed as an alternative to fusion bonding. However, the adhesive layers add to the thickness of the catheter and increase its rigidity at the region of the bonds. Moreover, adhesive bonds are known to be generally inferior to fusion bonds.

[0009] The use of laser energy to seal two elements together has been disclosed in other fields such as packaging. See for example European Patent Publication 0 087 403 and U.S. Patent No. 3,769,117. However, these prior processes and products are not suitable for bonding balloons to the shafts of a balloon dilatation catheter.

[0010] Therefore, it is an object of the present invention to provide a process for forming balloon catheters with fusion bonds, with minimal heat conduction away from the bond sites.

[0011] Another object of the invention is to bond dilation balloons to catheters in a manner to reduce thermal shock to the balloon cones, resulting in softer, more flexible dilatation balloons.

[0012] A further object is to provide balloon catheters with proximal and distal fusion bonds that are narrow, yet able to withstand high burst pressures.

[0013] Yet another object is to provide a balloon catheter more maneuverable along arteries and at reduced

risk of trauma to the arteries.

Summary of the Invention

[0014] To achieve these and other objects, there is provided a balloon catheter as claimed in claim 17. Particular embodiments of the balloon catheter according to claim 17 are the subject of the dependent claims 18 to 15. Such a balloon catheter includes an elongate pliable length of catheter tubing formed of a polymeric material and having a proximal end and a distal end. The balloon catheter further includes a polymeric dilatation balloon mounted to the catheter tubing near the distal end and in surrounding relation to the catheter tubing. The balloon includes a medial region, and proximal and distal shaft regions. Each shaft region is substantially smaller in diameter than the medial region. The balloon further includes proximal and distal tapered regions between the medial region and the proximal and distal neck regions, respectively. Each tapered region diverges in the direction from its associated shaft region to the medial region. Annular proximal and distal fluid tight fusion bonds are formed between the catheter tubing and the proximal and distal shaft regions, respectively. Each of the proximal and distal fusion bonds is within (.030 inches) 0.0762 cm of its associated one of the proximal and distal tapered regions. Moreover, each of the distal tapered regions is substantially free of crystallization.

[0015] Preferably, the axial dimension of the distal fusion bond is at most (.030 inches) 0.0762 cm. It is less than (.030 inches) 0.0762 cm from the distal tapered region. This facilitates construction of a balloon catheter having a distal tip length of less than (0.06 inches) 0.152 cm, and more preferably less than (0.03 inches) 0.0762 cm.

[0016] The shorter distal tip, in combination with the virtual absence of crystallization or stiffening of the adjacent balloon tapered region, results in substantially improved catheter maneuverability through convoluted vessels, during catheter insertion and also during catheter withdrawal. The catheter may be inserted into and used in vessels heretofore deemed inaccessible, and at substantially less risk of injury to the intima.

[0017] The reduced length distal lip is achieved while maintaining the integrity of the bond, due to a unique process for forming a fluid tight seal between a polymeric body and a polymeric dilatation member surrounding the body. Accordingly, the invention also provides a process as claimed in claim 1. Particular embodiments of the process according to claim 1 are the subject of the dependent claims 2 to 16. The process includes the following steps:

a. positioning a dilatation member of polymeric material along and in surrounding relation to a body of polymeric material, with the dilatation member and body aligned to place a first surface portion of the dilatation member and a second surface portion of the body in a contiguous and confronting relation;

b. generating substantially monochromatic energy at a wavelength selected to at least approximately match a wavelength of maximum spectral absorption of the polymeric materials forming the dilatation member and body;

c. controllably directing the monochromatic energy into the body and the dilatation member to concentrate the amount of monochromatic energy in a narrow bond site circumscribing the body and running along the interface of the first and second surface portions, thus to melt the polymeric materials along the bond site and the immediate region of the bond site; and

d. allowing the previously melted polymeric material to cool and solidify to form a fusion bond between the body and dilatation member.

[0018] A preferred process employs a round body and an annular dilatation member, whereby the interface of the first and second surfaces is annular. A beam of the monochromatic energy is focused, with the focal area of the beam substantially at the interface. Then, the focal area is moved in a annular path along the interface, relative to the body and the dilatation member. This is readily accomplished by mounting the body and dilatation member substantially concentrically on an axis, and rotating the body and dilatation member about the axis while maintaining the beam stationary. Alternatively, the body and dilation member are maintained stationary, while optomechanical means are employed to rotate the beam about the axis.

[0019] The preferred monochromatic energy is laser energy having a wavelength in the far infrared range, most preferably about 10.6 microns. Preferred polymeric materials, e.g. Hytrel, (polyester) for the catheter tubing and polyethylene terephthalate for the balloon, are highly absorptive of energy at this wavelength, The high absorption prevents any substantial conduction of heat from the bond site in either direction axially of the catheter. This reduces the energy required to form the fusion bond, and prevents any substantial crystallization and hardening of material in either direction from the bond site.

[0020] A CO_2 laser is used to provide a radiant energy beam at the preferred wavelength, and preferably operated in the tem_{00} mode. In this mode, the focal area of the beam has a Gaussian distribution, further enhancing the concentration of heat at the bond site.

[0021] Thus, in accordance with the present invention, consistent and reliable fusion bonds are formed between catheters and dilatation balloons, The bonds are narrow in axial dimension, with relatively slight thermal shock and stiffening to the material near the bond site, in particular the cones or tapered regions of the dilatation balloon. The result is a balloon catheter that is more maneuverable, more pliable for a more complete

evacuation of radiopaque dye, and more able to withstand high burst pressures.

Brief Description of the Drawings

[0022] For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which:

Figure 1 is a side elevational view of the distal region of a balloon catheter constructed in accordance with the present invention;
Figure 2 is an enlarged sectional elevational of a portion of Figure 1;
Figure 3 is a schematic view of tooling employed in the manufacture of the balloon catheter;
Figures 4-9 are schematic illustrations of various steps in the catheter assembly process;
Figure 10 is a schematic view of an alternative embodiment approach to manufacturing the balloon catheter,
Figure 11 is a schematic view of a laser generator and an array of optical fibers for supplying laser energy to the fixture according to a further embodiment approach;
Figure 12 is a side elevation of the distal end region of a balloon catheter and the fixture;
Figure 13 is a forward sectional elevation of the fixture; and
Figure 14 is a side sectional elevation of part of an alternative embodiment fixture.

Detailed Description of the Invention

[0023] Turning now to the drawings, there is shown in Figure 1 a balloon catheter 16, more particularly its distal end region. The balloon catheter includes an elongate and pliable length of catheter tubing 18 constructed of a body compatible polymeric material, preferably a polyester such as that sold under the brand name Hytrel. Other suitable materials include polyolefins, polyamides and thermoplastic polyurethanes, and copolymers of these materials. A dilatation balloon 20 surrounds catheter tubing 18 along the distal end region. The dilatation balloon is shown in its fully expanded or dilated configuration, as when the balloon contains a fluid, supplied under pressure to the balloon interior through a balloon inflation lumen (not shown) open to the proximal end of catheter tubing 18 and to the balloon interior.

[0024] When fully expanded, dilatation balloon 20 includes a main body or medial region 22, essentially an axially extended cylinder substantially concentric about the catheter tubing, and with a diameter substantially larger than that of the tubing, for example (.060-.13 inches) 0.152-0.330 cm as compared to an outside diameter in the range of (.040-.055 inches) 0.102-0.139 cm for catheter tubing 18. The appropriate balloon and catheter tubing diameters vary, depending upon factors such as the size of the vessel or other body cavity, and the procedure involved, At opposite ends of the medial region are a proximal tapered region or cone 24, and a distal tapered region or cone 26. The proximal cone converges in the direction away from the medial region toward an annular proximal neck region or shaft 28. The inner diameter of shaft 28 is substantially equal to the outer diameter of catheter tubing 18 in the region of the shaft, to provide an annular interface region along which the interior surface of shaft 28 and the exterior surface of tubing 18 confront one another and are contiguous.

[0025] Similarly, distal cone 26 converges in the distal direction from medial region 22 to a distal neck region or shaft 30. The distal shaft has an inner diameter substantially equal to the outer diameter of catheter tubing 18 in the region of the distal shaft. Consequently, the diameter of distal shaft 30 typically is less than the inner diameter of proximal shaft 28, because the catheter tubing is narrower along the distal shaft, e.g. due to the termination of the balloon inflation lumen proximally of shaft 30.

[0026] Dilatation balloon 20 preferably is constructed of a polymeric material that is sufficiently pliable or formable to readily achieve the enlarged configuration, yet is relatively inexpansible, i.e. tending to maintain the configuration shown in Figure 1 under increased fluid pressure within the balloon. Polyethylene terephthalate (PET) is a preferred material for dilatation balloon 20. Among other suitable materials are nylon, polyolefin and their copolymers.

[0027] As seen in Figure 2, catheter tubing 18 has a central lumen 32 to accommodate a guide wire (not shown) and, if desired, to provide a path for supplying drugs from the proximal end of the catheter tubing to a treatment site. A broken line at 34 indicates the proximal boundary of a fusion bond 36 between catheter tubing 18 and distal shaft 30. Fusion bond 36 is annular, and is located along the interface between the distal shaft and the catheter tubing. More particularly, the polymeric material along the inside surface of shaft 30 and the polymeric material along the exterior surface of tubing 18 become fused and form the bond as they cool and solidify, to provide a fluid tight seal between the catheter tubing and the dilatation balloon.

[0028] Preferably, bond 36 has an axial dimension of at most (.030 inches) 0.0762 cm. It is within (.030 inches) 0.0762 cm of distal cone 26, for a length of the catheter distal tip (including distal shaft 30 and the distal end of catheter tubing 18) of at most (.060 inches) 0.152 cm. More preferably, the axial dimension of the bond is about (.020 inches) 0.0508 cm, and the bond is within (.010 inches) 0.0254 cm of cone 26. Further, the distal cone is substantially free of the crystallization that results from thermal shock from the heat of bond formation. One sign of crystallization is tactile, namely a hardness or stiffness in the cones when crystallized. A

related indication can be observed in connection with tracking fixtures for testing the ability of a catheter to negotiate serpentine channels formed in the fixtures. Also, crystallized cones, as compared to cones free of crystallization, have a substantially more pronounced tendency to warp or form asymmetrically. Crystallization imparts an undesirable stiffness to the polymeric material, increasing the difficulty in maneuvering the balloon catheter through convoluted arteries. Such stiffness in the balloon also interferes with a complete evacuation of radiopaque dye or other fluid from the balloon following dilitation. An incompletely evacuated dilitation balloon is more difficult to withdraw after an angioplasty procedure. Thus, freedom from crystallization and stiffness, and a shorter distal tip, provide substantially improved catheter manoeuverability.

[0029] By comparison, balloon catheters manufactured according to the conventional approach with heated copper jaws require distal tips in which the bond, alone, has an axial length of at least (.070 inches) 0.178 cm, and further must be spaced apart from the distal cone at least (.030 inches) 0.0762 cm due to the undesirable crystallization and stiffening of the balloon. In fact, the heated jaws cause substantial crystallization in the distal cone, in spite of the (.030 inch) 0.0762 cm spacing.

[0030] In accordance with the present invention, fusion bonds between the catheter tubing and dilatation balloon are formed by a noncontact process, resulting in bonds that are much narrower yet withstand burst pressure to the same degree as conventional bonds. Moreover, as compared to conventionally formed bonds, bonds formed according to the present invention can be positioned substantially closer to the cones of the dilatation balloon, without the crystallization or attendant stiffening.

[0031] Apparatus employed in forming the balloon catheter is illustrated diagrammatically in Figure 3. The apparatus includes an elongate mandril 38 formed of stainless steel. The outside diameter of mandril 38 is approximately equal to the diameter of central lumen 32, so that the mandril receives catheter tubing 18 in sliding or slip fit fashion. The mandril is removably clamped within a jig or chuck 40, rotatable to rotate the mandril about a horizontal axis 42.

[0032] A system for directing monochromatic energy onto the mandril includes a laser source 44 generating a laser beam 46 with a wavelength in the far infrared range. Preferably the laser is a CO_2 laser, in which case the wavelength of beam 46 is about 10.6 microns. The beam is directed through a concave-concave lens 48 which expands the beam, and then to a convex-convex lens 50 which collimates the beam. The collimated beam is directed through a convex-convex lens 52, which focuses the beam at a focal point or area 54 slightly radially outwardly of the mandril exterior surface.

[0033] Near the free end of mandril 38 is a mandril guide 56 having an opening 58 slightly larger in diameter than the mandril. Guide 56 is movable axially of the mandril, between the location illustrated in which it is completely removed from mandril 38, and a support position in which the free end of the mandril is captured within opening 58, thus to stabilize the mandril rotation.

[0034] The assembly of a balloon catheter 60 begins with the placement of a length of catheter tubing 62 onto the mandril, whereupon the catheter tubing is slid along the mandril to the right as viewed in Figure 3, until the distal end of the catheter tubing abuts jig 40 as shown in Figure 4. Next, a relatively short ((.030 inches) 0.0762 cm) length of heat shrink tubing 64, preferably constructed of a polyolefin, is positioned at least near the jig, surrounding the catheter tubing as shown in Figure 5. Then, a dilatation balloon 66 is fitted onto and about the catheter tubing, and moved slidably until a distal shaft 68 of balloon 66 abuts jig 40. This involves inserting the distal shaft within heat shrink tubing 64 as shown in Figure 6. Finally, mandril guide 56 is moved rightwardly as viewed in these figures, until mandril 38 is captured within opening 58. As seen from Figure 7, heat shrink tubing 64 surrounds distal shaft 68, with a proximal portion of the heat shrink tubing overlapping the distal end region of a distal cone 70. If desired, heat shrink tubing 64 can be of a sufficient length to abut jig 40 when in the position shown.

[0035] Of primary importance, however, is a proper alignment of dilatation balloon 66 for bonding. Preferably, laser source 44 and the accompanying optics are movable axially of the mandril relative to jig 40, to selectively align the laser system with respect to the jig. For example, given an intended fusion bond width of (.030 inches) 0.0762 cm and an axial distance of (.010 inches) 0.0254 cm between the distal cone and the bond site, the laser system is positioned relative to the jig such that beam 46 is aligned on the intended center of the bond relative to the distal cone, i.e. at (.025 inches) 0.0635 cm from the cone.

[0036] With the catheter tubing, dilatation balloon and heat shrink tubing properly positioned and with the laser system properly aligned, laser source 44 is fired to generate beam 46 while mandril 38 is rotated. Lens 52 focuses beam 46 to position focal area 54 as illustrated in Figure 8, i.e. at the interface of catheter tubing 62 and distal shaft 68 of the dilatation balloon. Accordingly, the laser energy is concentrated along an annular bond site 72, defined by the rotation of the mandril, catheter tubing and balloon shaft relative to beam 46.

[0037] Several factors facilitate concentration of the laser energy, resulting in effective bonds at relatively low wattage for laser source 44 and a relatively short duration for laser bonding. Of course, the focusing concentrates the energy of beam 46. Laser source 44 preferably is operated in the tem_{00} mode, which results in a focal area having a Gaussian energy distribution, with maximum energy at the center of the local area. Further, the wav length of the laser energy and the polymeric materials of dilatation balloon 66 and catheter

tubing 62 are matched, in the sense that both the PET and the Hytrel polyester have a high absorptivity for energy at the selected wavelength of 10.6 microns.

[0038] In practice, "matching" involves consideration of the cost and availability of laser sources as well as the polymeric materials of the catheter tubing and the dilatation balloon. Information on the adsorptivity of various materials, with respect to wavelength of the energy, is available, for example in The Infrared Spectra Atlas of Monomers and Polymers, published by Sadtler Research Laboratories. In general, polymeric materials do not absorb energy uniformly, but rather exhibit bands of markedly increased absorptivity. For example, both polyethylene and polypropylene exhibit high absorptivity of energy at about 3.4 microns in wavelength, due to the CH_2 groups in these polymers. As polymers become more complex, so do their energy absorption spectra. Polyesters exhibit a band of absorption ranging from about 7-11 microns, a range that encompasses the 10.6 micron wavelength of laser beam 46. The tendency in polymers to exhibit wavelength-selective absorption is observed not only in connection with infrared energy, but throughout the electromagnetic spectrum.

[0039] As a result of these factors, heat sufficient to fuse an outer surface 74 of catheter tubing 62 and an inner surface 76 of distal shaft 68 is generated at a laser power of less than 10 watts, more particularly in the range of 3-4 watts. Mandril 38 is rotated at about 400 rpm during bonding, which tends to evenly distribute the heat about the bond site. A duration of from about .5 seconds to about 3 seconds of laser energy application has been found satisfactory for forming bonds that can withstand burst pressures exceeding (400 pounds per square inch) 2.758 megapascal, and the degree of control over the laser yields a high degree of consistency among the bonds. After the fused material cools and solidifies, heat shrink tubing 64 is removed.

[0040] A further benefit arises from the absorptivity match of the laser wavelength and polymeric materials of the catheter tubing and dilatation balloon. Due to the high absorptivity of these polymeric materials at the chosen wavelength, there is virtually no substantial conduction of heat in either axial direction away from the bond site. Portions of the tubing and balloon near the bond are not subject to undue heating that leads to crystalization and stiffening of the polymeric materials. Thus, a distal bond can be positioned within (.010 inches) 0.0254 cm of distal cone 70 without any substantial crystallization or stiffening of the cone. As noted above, bonding with heated copper jaws requires a spacing of at least (.030 inches) 0.0762 cm between the bond and the distal cone due to crystallization and stiffening. As a result, catheter balloons assembled according to the above described process can have substantially shorter distal tips and softer distal cones, for enhanced maneuverability in narrow, convoluted arteries.

[0041] Figure 9 illustrates a further step in the process, in which the distal bond is formed with an axial dimension larger than intended for the finished catheter, but with a controlled spacing from the distal cone. In this event, the steps discussed above are repeated without any substantial change. Then, the completed balloon catheter is inserted by its distal tip into a cutting fixture 78 (Figure 9) with the distal tip contained in an opening 80 through the fixture. With distal cone 70 abutting the fixture as illustrated, an excess length portion 82 of the distal tip extends beyond an end wall 84 of the fixture, and is conveniently cut away from the remainder of the catheter with a blade 86 movable along the end wall.

[0042] Figure 10 illustrates an alternative means for concentrating the laser energy at an annular bond site. A length of catheter tubing 88, a dilatation balloon 90 and heat shrink tubing 92 are supported on an elongate stationary pin 94. A laser source 96, also stationary, generates a beam 98 of the preferred wavelength of 10.6 microns. Beam 98 is directed through a concave-concave diverging lens 100, and then through a convex-convex lens 102 to collimate the beam. The collimated beam is diverted by a series of planar reflectors at 104, 106 and 108, and finally through a convex-convex focusing lens 110, which locates the beam at the interface between catheter tubing 88 and dilatation balloon 90.

[0043] With the tubing and balloon stationary, the required relative movement is achieved by rotating beam 98. More particularly, planar reflectors 104, 106 and 108 and lens 110 are mounted integrally with respect to each other, but rotatable relative to pin 94.

[0044] Figures 11-13 illustrate an alternative approach to forming the fusion bond, in which a length of catheter tubing 112, a dilatation balloon 114 and heat shrink tubing 116 are positioned within a bonding fixture 118 for directing multiple beams of laser energy onto the bond site. Fixture 118 includes a central opening 120 for receiving the tubing and balloon shaft, and further includes six radial openings for accommodating six optical fibers 122-132. The optical fibers are connected in common to a laser energy source 134. Thus, a single beam is effectively split into six identical beams, distributed uniformly about the bond area and slightly overlapping one another along the annular bond site to insure substantially even energy distribution.

[0045] Due to the use of fiber optics in this system, it is preferable to generate laser energy at a wavelength in the near infrared range, more particularly at about 1.06 microns. The near infrared wavelength, as compared to the far infrared wavelength previously discussed, is not as well matched to the absorption spectra of the polymeric materials forming the dilatation balloon and catheter tubing. Consequently, a coating of a dark ink or polymeric film is applied to the exterior of catheter tubing 112 at the bond site, and thus provides enhanced energy absorption at the interface, as is best seen at 136 in Figure 12.

[0046] The system in Figures 11-13 forms satisfactory

bonds without focusing optics, so long as sufficient power (less than 10 watts) is provided in laser source 134 and the optical fiber terminations are positioned sufficiently close to the dilatation balloon and tubing. If desired, however, the laser energy can be more effectively concentrated at the bond site with focusing optics, e.g. a planar-convex lens at the tip of each optical fiber near the bond site, as shown at 138 in connection with an optical fiber 140 in a fixture 142 similar to fixture 118. Lens 138 of course is selected to focus the beam at the interface between a length of catheter tubing 144 and a dilatation balloon 146 along the bond site.

[0047] One apparent advantage of the bonding approach shown in Figures 11-14 is the ability to maintain the fixture, beams, and polymeric components stationary as the bond is formed. A further advantage is that multiple beam fixtures can be fashioned to accommodate noncircular bonds, e.g. for catheter tubing having the cross section of an oval or ellipse in the bond region.

[0048] While only the distal bond is discussed in detail, it is to be appreciated that forming a proximal bond between the proximal shaft of the dilatation balloon and catheter tubing is substantially the same. The only significant difference is the absence of any step similar to the cutting of the distal tip to a preferred length as described in connection with Figure 9. Proximal and distal bonds formed according to the present invention have been found to withstand substantial burst pressures, specifically in the range of about (425 pounds per square inch) 2.930 megapascal. In fact, under testing the dilatation balloon itself tends to burst, prior to the failure of either fusion bond, even with the axial dimension of the distal fusion bond as low as (.020 inches) 0.0508 cm. Uniformity of the bonds is enhanced by fusion with concentrated, monochromatic energy. Finally, concentration of the energy in combination with the high absorption of the selected wavelength, virtually eliminates unwanted heat conduction in axial directions away from the bond site, permitting placement of bonds adjacent to the proximal and distal cones of the dilatation balloon, without any substantial crystallization and stiffening of the cones.

[0049] The preferred embodiment balloon catheter 16 is of coaxial construction. It is to be understood that alternative catheter constructions, for example multilumen catheters, can be manufactured according to the process described above, within the scope of the present invention, as laid down in the claims.

Claims

1. A process for forming a fluid tight seal between a polymeric body (18) and a polymeric dilatation member (20) surrounding the body (18)

   comprising positioning the dilatation member along and in surrounding relation to the body (18) with the dilatation member and body aligned to place a first surface portion of the dilatation member and a second surface portion of the body in a contiguous and confronting relation,

   generating substantially monochromatic energy at a wavelength selected to at least approximately match a wavelength of high spectral absorption of at least one of the polymeric materials forming the dilatation member and body,

   controllably directing the monochromatic energy onto the body and the dilatation member to concentrate the monochromatic energy in a narrow bond site circumscribing the body and running along the interface of the first and second surface portions, thus to melt the polymeric materials along said bond site and the immediate region thereof

   and allowing the previously melted polymeric material to cool and solidify to form a fusion bond (36) between the body and dilatation member,

   wherein the body is a length of catheter tubing (18) and the dilitation member is a catheter balloon positioned along a distal end region of the catheter tubing (18) and including proximal and distal neck portions (28, 30), a medial region (22) having a diameter substantially larger than that of the neck portions, and proximal and distal tapered conical regions (24,26) between the medial region and respective neck regions,

   and wherein the step of directing the monochromatic energy includes forming the bond site along the interface between the proximal or distal neck and the catheter tubing (18) separated from the proximal or distal tapered conical region, respectively, by an axial distance of less than 0.0762 cm (0.030 inches).

2. The process of claim 1 wherein the wavelength of the monochromatic energy is selected to approximately match wavelengths of high spectral absorption of the polymeric materials forming both the dilatation member and the body.

3. The process of claim 1 or 2 wherein said interface of the first and second surfaces is annular and the step of directing the monochromatic energy includes focusing the beam to position a focal area of the beam substantially at the interface and moving the focal area, relative to the body and the dilatation member, in an annular path along the interface to define said bond site.

4. The process of claim 3 wherein the step of moving the focal area includes mounting the body and dilatation member substantially concentrically on an

axis and rotating the body and dilatation member about the axis while maintaining the b am stationary.

5. The process of claim 4 wherein the focal area is circular and has a diameter of about 0.254 cm (0.10 inches) and wherein the monochromatic energy is generated using a laser (44) and the power of the laser is in the range of from 1-10 watts.

6. The process of claim 5 wherein the body and dilatation member are rotated at a speed of about 400 rpm for a duration in the range of from 0.5 to 3 seconds.

7. The process of claim 3 wherein the step of rotating the focal area relative to the body and dilatation member includes mounting the body concentrically about an axis and optomechanically rotating the beam about the axis while maintaining the body and dilatation member stationary.

8. The process of any one of the preceding claims wherein the monochromatic energy is laser energy having a wavelength in the far infrared range.

9. The process of claim 8 wherein the wavelength of the laser energy is approximately 10.6 microns.

10. The process of claim 1 or 2 wherein the step of directing the monochromatic energy includes providing multiple optical carriers (122, 124, 126, 128, 130, 132) arranged generally radially about the body and the dilatation member and providing the monochromatic energy to the optical carriers simultaneously whereby the energy is directed in multiple beams that penetrate the body and dilatation member assembly at least to the interface.

11. The process of claim 10 wherein the multiple beams overlap one another at the interface.

12. The process of claim 10 or 11 wherein the monochromatic energy comprises laser energy in the near infrared range.

13. The process of claim 12 including the further step of, prior to positioning the polymeric dilatation member, coating at least one of said first and second surfaces with a polymeric film highly absorbant of energy in the near infrared range of wavelength.

14. The process of claim 1 or 2 including the further step of positioning a polymeric shrink fit member (64) in surrounding relation to the dilatation member and body before said step of directing the monochromatic energy.

15. The process of claim 14 including the further step of removing the polymeric shrink fit member following the step of allowing the melted polymeric material to cool and solidify.

16. The process of any one of the preceding claims wherein the bond site is formed along the interface between the distal neck and the catheter tubing.

17. A balloon catheter comprising

an elongate pliable length of catheter tubing (18) formed of a polymeric material and having a proximal end and a distal end,
a polymeric dilatation balloon (20) mounted to the catheter tubing (18) near the distal end and in surrounding relation to the catheter tubing,
said balloon including a medial region (22), proximal and distal neck regions (28,30) each substantially smaller in diameter than the medial region, and proximal and distal tapered regions (24,26) between the medial region and the proximal and distal neck regions, respectively, each tapered region diverging in the direction from its associated neck region to the medial region, and
a proximal or distal fluid tight fusion bond between the catheter tubing (18) and the proximal or distal neck region, respectively, wherein the proximal or distal fusion bond is within 0.0762 cm (0.030 inches) of its associated tapered region and wherein the associated tapered region is substantially free of crystallisation.

18. The balloon catheter of claim 17 wherein the fusion bond is formed by a process as claimed in claim 1 or 2.

19. The balloon catheter of claim 17 or 18 wherein the inner diameter of the proximal or distal neck portion is substantially equal to the outer diameter of the catheter tubing (18) in the region of the proximal or distal fusion bond.

20. The balloon catheter of claim 19 wherein the catheter tubing, neck regions and fusion bonds are annular.

21. The balloon catheter of claim 20 wherein the axial dimension of the distal fusion bond is at most 0.0762 cm (0.030 inches).

22. The balloon catheter of claim 21 wherein the axial dimension of the distal fusion bond is about 0.0508 cm (0.020 inches).

23. The balloon catheter of claim 22 wherein the distal

fusion bond is less than 0.0254 cm (0.010 inches) from the distal tapered region.

24. The balloon catheter of claim 17 or 18 wherein the catheter tubing (18) comprises an extrusion of at least one thermoplastic polymeric material chosen from the group consisting of polyesters, polyolefins, polyamides, thermoplastic polyurethanes and their copolymers.

25. The balloon catheter of claim 24 wherein the balloon is formed of at least one of the materials from the group consisting of polyethylene terephthalate, nylon, polyolefin, and their copolymers.

Patentansprüche

1. Verfahren zur Herstellung einer fluiddichten Abdichtung zwischen einem Polymerkörper (18) und einem den Körper (18) umgebenden Polymerdilatationsteil (20) mit den folgenden Schritten:

   Positionieren des Dilatationsteils längs des Körpers (18) und in Umgebungsbeziehung mit ihm, wobei das Dilatationsteil und der Körper so ausgerichtet werden, daß ein erster Oberflächenabschnitt des Dilatationsteils und ein zweiter Oberflächenabschnitt des Körpers in einer angrenzenden und gegenüberliegenden Beziehung plaziert werden,
   Erzeugen von im wesentlichen monochromatischer Energie mit einer Wellenlänge, die so ausgewählt ist, daß sie mindestens annähernd einer Wellenlänge hoher spektraler Absorption mindestens eines der Polymermaterialien entspricht, die das Dilatationsteil und den Körper bilden, steuerbares Richten der monochromatischen Energie auf den Körper und das Dilatationsteil, um die monochromatische Energie in einer schmalen Verbindungsstelle zu konzentrieren, die den Körper umschreibt und längs der Grenzfläche des ersten und zweiten Oberflächenabschnitts verläuft, um so die Polymermaterialien längs der Verbindungsstelle und ihres unmittelbaren Bereichs zu schmelzen, und
   Abkühlen- und Verfestigenlassen des zuvor geschmolzenen Polymermaterials, um eine Schweißverbindung (36) zwischen dem Körper und dem Dilatationsteil herzustellen, wobei der Körper ein Stück Katheterschlauch (18) ist und das Dilatationsteil ein Katheterballon ist, der längs eines distalen Endbereichs des Katheterschlauchs (18) positioniert ist und einen proximalen und einen distalen Halsabschnitt (28, 30), einen medialen Abschnitt (22) mit einem wesentlich größeren Durchmesser als die Halsabschnitte sowie einen proximalen und einen distalen zulaufenden konischen Bereich (24, 26) zwischen dem medialen Bereich und jeweiligen Halsbereichen aufweist, und wobei der Schritt des Richtens der monochromatischen Energie den Schritt des Ausbildens der Verbindungsstelle längs der Grenzfläche zwischen dem proximalen oder distalen Hals und dem Katheterschlauch (18) umfaßt, die vom proximalen bzw. distalen sich verjüngenden, konischen Bereich um einen Axialabstand von weniger als 0,0762 cm (0,030 Inch) getrennt ist.

2. Verfahren nach Anspruch 1, wobei die Wellenlänge der monochromatischen Energie so ausgewählt ist, daß sie annähernd Wellenlängen hoher spektraler Absorption der Polymermaterialien entspricht, die sowohl das Dilatationsteil als auch den Körper bilden.

3. Verfahren nach Anspruch 1 oder 2, wobei die Grenzfläche der ersten und zweiten Oberfläche ringförmig ist und der Schritt des Richtens der monochromatischen Energie die folgenden Schritte aufweist: Fokussieren des Strahls, um einen Fokalbereich des Strahls im wesentlichen an der Grenzfläche zu positionieren, und Bewegen des Fokalbereichs relativ zum Körper und zum Dilatationsteil auf einem ringförmigen Weg längs der Grenzfläche, um die Verbindungsstelle zu bilden.

4. Verfahren nach Anspruch 3, wobei der Schritt des Bewegens des Fokalbereichs die folgenden Schritte aufweist: im wesentlichen konzentrisches Anordnen des Körpers und des Dilatationsteils auf einer Achse und Drehen des Körpers und des Dilatationsteils um die Achse, während der Strahl stationär bleibt.

5. Verfahren nach Anspruch 4, wobei der Fokalbereich kreisförmig ist und einen Durchmesser von etwa 0,254 cm (0,10 Inch) hat und wobei die monochromatische Energie unter Verwendung eines Lasers (44) erzeugt wird und die Leistung des Lasers im Bereich von 1-10 Watt liegt.

6. Verfahren nach Anspruch 5, wobei der Körper und das Dilatationsteil mit einer Drehzahl von etwa 400 U/min für eine Dauer im Bereich von 0,5 bis 3 Sekunden gedreht werden.

7. Verfahren nach Anspruch 3, wobei der Schritt des Drehens des Fokalbereichs relativ zum Körper und Dilatationsteil die folgenden Schritte aufweist: konzentrisches Anordnen des Körpers um eine Achse und optomechanisches Drehen des Strahls um die Achse, während der Körper und das Dilatationsteil stationär bleiben.

8. Verfahren nach einem der vorstehenden Ansprüche, wobei die monochromatische Energie Laserenergie mit einer Wellenlänge im fernen Infrarotbereich ist.

9. Verfahren nach Anspruch 8, wobei die Wellenlänge der Laserenergie etwa 10,6 Mikrometer beträgt.

10. Verfahren nach Anspruch 1 oder 2, wobei der Schritt des Richtens der monochromatischen Energie die folgenden Schritte aufweist: Bereitstellen mehrerer optischer Träger (122, 124, 126, 128, 130, 132), die allgemein radial um den Körper und das Dilatationsteil angeordnet sind, und gleichzeitiges Führen der monochromatischen Energie zu den optischen Trägern, wodurch die Energie in mehreren Strahlen gerichtet wird, die die Anordnung aus Körper und Dilatationsteil mindestens bis zur Grenzfläche durchdringen.

11. Verfahren nach Anspruch 10, wobei sich die mehreren Strahlen an der Grenzfläche überlappen.

12. Verfahren nach Anspruch 10 oder 11, wobei die monochromatische Energie Laserenergie im nahen Infrarotbereich aufweist.

13. Verfahren nach Anspruch 12 mit dem vor Positionieren des Polymerdilatationsteils durchgeführten weiteren Schritt des Beschichtens der ersten und/oder zweiten Oberfläche mit einem Polymerfilm, der Energie im nahen Infrarotwellenlängenbereich stark absorbiert.

14. Verfahren nach Anspruch 1 oder 2 mit dem weiteren Schritt des Positionierens eines Polymerschrumpfsitzteils (64) in Umgebungsbeziehung mit dem Dilatationsteil und dem Körper vor dem Schritt des Richtens der monochromatischen Energie.

15. Verfahren nach Anspruch 14 mit dem weiteren Schritt des Entfernens des Polymerschrumpfsitzteils nach dem Schritt des Abkühlen- und Verfestigenlassens des geschmolzenen Polymermaterials.

16. Verfahren nach einem der vorstehenden Ansprüche, wobei die Verbindungsstelle längs der Grenzfläche zwischen dem distalen Hals und dem Katheterschlauch ausgebildet wird.

17. Ballonkatheter mit

einem länglichen geschmeidigen Stück Katheterschlauch (18), der aus einem Polymermaterial gebildet ist und ein proximales Ende und ein distales Ende hat,
einem Polymerdilatationsballon (20), der am Katheterschlauch (18) nahe dem distalen Ende und in Umgebungsbeziehung mit dem Katheterschlauch angeordnet ist,
wobei der Ballon aufweist: einen medialen Bereich (22), einen proximalen und einen distalen Halsbereich (28, 30), die jeweils inen wesentlich kleineren Durchmesser als der mediale Bereich haben, sowie einen proximalen und einen distalen sich verjüngenden Bereich (24, 26) zwischen dem medialen Bereich und dem proximalen bzw. distalen Halsbereich, wobei jeder sich verjüngende Bereich von seinem zugehörigen Halsbereich in die Richtung zum medialen Bereich auseinandergeht, und
einer proximalen oder distalen fluiddichten Schweißverbindung zwischen dem Katheterschlauch (18) und dem proximalen bzw. distalen Halsbereich, wobei die proximale oder distale Schweißverbindung innerhalb 0,0762 cm (0,030 Inch) von ihrem zugehörigen sich verjüngenden Bereich liegt und wobei der zugehörige sich verjüngende Bereich im wesentlichen frei von Kristallisation ist.

18. Ballonkatheter nach Anspruch 17, wobei die Schweißverbindung durch ein Verfahren nach Anspruch 1 oder 2 hergestellt ist.

19. Ballonkatheter nach Anspruch 17 oder 18, wobei der Innendurchmesser des proximalen oder distalen Halsabschnitts im wesentlichen gleich dem Außendurchmesser des Katheterschlauchs (18) im Bereich der proximalen oder distalen Schweißverbindung ist.

20. Ballonkatheter nach Anspruch 19, wobei der Katheterschlauch, die Halsbereiche und die Schweißverbindungen ringförmig sind.

21. Ballonkatheter nach Anspruch 20, wobei das Axialmaß der distalen Schweißverbindung höchstens 0,0762 cm (0,030 Inch) beträgt.

22. Ballonkatheter nach Anspruch 21, wobei das Axialmaß der distalen Schweißverbindung etwa 0,0508 cm (0,020 Inch) beträgt.

23. Ballonkatheter nach Anspruch 22, wobei die distale Schweißverbindung weniger als 0,0254 cm (0,010 Inch) vom distalen sich verjüngenden Bereich entfernt ist.

24. Ballonkatheter nach Anspruch 17 oder 18, wobei der Katheterschlauch (18) eine Extrusion aus mindestens einem thermoplastischen Polymermaterial aufweist, das aus der Gruppe ausgewählt ist, die aus Polyestern, Polyolefinen, Polyamiden, thermoplastischen Polyurethanen und deren Copolymeren

besteht.

25. Ballonkatheter nach Anspruch 24, wobei der Ballon aus mindestens einem der Materialien aus der Gruppe gebildet ist, die aus Polyethylenterephthalat, Nylon, Polyolefin und deren Copolymeren besteht.

Revendications

1. Procédé pour former un joint étanche aux fluides entre un corps polymère (18) et un élément de dilatation polymère (20) entourant le corps (18),

   comprenant les étapes consistant à positionner l'élément de dilatation le long du corps (18) en entourant celui-ci, l'élément de dilatation et le corps étant alignés de manière à placer une première partie de surface de l'élément de dilatation et une seconde partie de surface du corps en relation contigue et opposée, à générer une énergie sensiblement monochromatique à une longueur d'onde choisie pour correspondre au moins approximativement à une longueur d'onde d'absorption spectrale élevée d'au moins un des matériaux polymères formant l'élément de dilatation et le corps,
   à diriger de manière contrôlée l'énergie monochromatique sur le corps et l'élément de dilatation pour concentrer l'énergie monochromatique sur un site de liaison étroit entourant le corps et s'étendant le long de l'interface des première et seconde parties de surface, de manière à faire fondre les matériaux polymères le long dudit site de liaison et sa région immédiate, et
   à permettre au matériau polymère précédemment fondu de refroidir et de se solidifier pour former une liaison de fusion (36) entre le corps et l'élément de dilatation,
   dans lequel le corps est une longueur de tube de cathéter (18) et l'élément de dilatation est un ballonnet de cathéter disposé le long d'une région d'extrémité distale du tube de cathéter (18) et comprenant ces parties de col proximale et distale (28, 30), une région médiane (22) ayant un diamètre sensiblement plus grand que celui des parties de col, et des régions coniques proximale et distale (24, 26) entre la région médiane et les régions de col respectives,
   et dans lequel l'étape consistant à diriger l'énergie monochromatique comprend la formation du site de liaison le long de l'interface entre le col proximal ou distal et le tube de cathéter (18) séparé de la région conique proximale ou distale, respectivement, d'une distance axiale de moins de 0,0762 cm (0,030 pouce).

2. Procédé selon la revendication 1, dans lequel la longueur d'onde de l'énergie monochromatique est choisie de manière à correspondre approximativement à des longueurs d'onde d'absorption spectrale élevée des matériaux polymères formant à la fois l'élément de dilatation et le corps.

3. Procédé selon la revendication 1 ou 2, dans lequel ladite interface des première et seconde surfaces est annulaire et l'étape consistant à diriger l'énergie monochromatique comprend la focalisation du faisceau pour positionner une zone focale du faisceau sensiblement à l'interface et le déplacement de la zone focale par rapport au corps et à l'élément de dilatation, dans un trajet annulaire le long de l'interface pour définir ledit site de liaison.

4. Procédé selon la revendication 3, dans lequel l'étape de déplacement de la zone focale comprend le montage du corps et de l'élément de dilatation sensiblement concentriquement sur un axe et la mise en rotation du corps et de l'élément de dilatation autour de l'axe tout en maintenait le faisceau immobile.

5. Procédé selon la revendication 4, dans lequel la zone focale est circulaire et a un diamètre d'environ 0,254 cm (0,10 pouce) et dans lequel l'énergie monochromatique est générée en utilisant un laser (44) et la puissance du laser se situe dans la plage de 1-10 watts.

6. Procédé selon la revendication 5, dans lequel le corps et l'élément de dilatation sont soumis à une rotation à une vitesse d'environ 400 tr/min pendant une période de temps dans la plage de 0,5 à 3 secondes.

7. Procédé selon la revendication 3, dans lequel l'étape de mise en rotation de la zone focale par rapport au corps et à l'élément de dilatation comprend le montage du corps concentriquement autour d'un axe et la mise en rotation optomécanique du faisceau autour de l'axe tout en maintenant le corps et l'élément de dilatation immobiles.

8. Procédé selon l'une quelconque des revendications précédentes, dans lequel l'énergie monochromatique est une énergie de laser ayant une longueur d'onde dans la plage de l'infrarouge lointain.

9. Procédé selon la revendication 8, dans lequel la longueur d'onde de l'énergie de laser est approximativement de 10,6 microns.

10. Procédé selon la revendication 1 ou 2, dans lequel

l'étape consistant à diriger l'énergi monochromatique comprend la mise en oeuvr de multiples supports optiques (122, 124, 126, 128, 130, 132) agencés en général radialement autour du corps et de l'élément de dilatation et à délivrer l'énergie monochromatique aux supports optiques simultanément, de sorte que l'énergie soit dirigée en faisceaux multiples qui pénètrent dans l'ensemble formé du corps et de l'élément de dilatation, au moins à l'interface.

11. Procédé selon la revendication 10, dans lequel les faisceaux multiples se chevauchent l'un l'autre à l'interface.

12. Procédé selon la revendication 10 ou 11, dans lequel l'énergie monochromatique comprend une énergie de laser dans la plage du proche infrarouge.

13. Procédé selon la revendication 12, comprenant l'autre étape consistant, après positionnement de l'élément de dilatation polymère, à revêtir au moins une desdites première et seconde surfaces d'un film polymère absorbant fortement l'énergie dans la plage de longueurs d'onde du proche infrarouge.

14. Procédé selon la revendication 1 ou 2, comprenant l'autre étape de positionnement d'un élément polymère à ajustement fretté (64) entourant l'élément de dilatation et le corps avant ladite étape consistant à diriger l'énergie monochromatique.

15. Procédé selon la revendication 14, comprenant l'autre étape d'élimination de l'élément polymère à ajustement fretté après l'étape consistant à laisser le matériau polymère fondu refroidir et se solidifier.

16. Procédé selon l'une quelconque des revendications précédentes, dans lequel le site de liaison est formé le long de l'interface entre le col distal et le tube de cathéter.

17. Cathéter à ballonnet comprenant :

une longueur flexible allongée de tube de cathéter (18) formée d'un matériau polymère et ayant une extrémité proximale et une extrémité distale,
un ballonnet de dilatation polymère (20) monté sur le tube de cathéter (18) près de l'extrémité distale en entourant le tube de cathéter,
ledit ballonnet comprenant une région médiane (22), des régions de col proximale et distale (28, 30), chacune de diamètre sensiblement plus petit que la région médiane, et des régions coniques proximale et distale (24, 26) entre la région médiane et les régions de col proximale et distale, respectivement, chaque région conique divergeant dans la direction de sa région de col associée à la région médiane, et
une liaison de fusion proximale ou distale étanche aux fluides entre le tube de cathéter (18) et la région de col proximale ou distale, respectivement, dans lequel la liaison de fusion proximale ou distale se situe à 0,0762 cm (0,030 pouce) de sa région conique associée et dans lequel la région conique associée est sensiblement exempte de cristallisation.

18. Cathéter à ballonnet selon la revendication 17, dans lequel la liaison de fusion est formée par un procédé selon la revendication 1 ou 2.

19. Cathéter à ballonnet selon la revendication 17 ou 18, dans lequel le diamètre interne de la partie de col proximale ou distale est sensiblement égal au diamètre externe du tube de cathéter (18) dans la région de la liaison de fusion proximale ou distale.

20. Cathéter à ballonnet selon la revendication 19, dans lequel le tube de cathéter, les régions de col et les liaisons de fusion sont annulaires.

21. Cathéter à ballonnet selon la revendication 20, dans lequel la dimension axiale de la liaison de fusion distale est au maximum de 0,0762 cm (0,030 pouce).

22. Cathéter à ballonnet selon la revendication 21, dans lequel la dimension axiale de la liaison de fusion distale est d'environ 0,0508 cm (0,020 pouce).

23. Cathéter à ballonnet selon la revendication 22, dans lequel la liaison de fusion distale est située à moins de 0,0254 cm (0,010 pouce) de la région distale conique.

24. Cathéter à ballonnet selon la revendication 17 ou 18, dans lequel le tube de cathéter (18) comprend une extrusion d'au moins un matériau polymère themoplastique choisi dans le groupe constitué de polyesters, de polyoléfines, de polyamides, de polyuréthannes thermoplastiques et de leurs copolymères.

25. Cathéter à ballonnet selon la revendication 24, dans lequel le ballonnet est formé d'au moins un des matériaux choisis dans le groupe constitué de poly (téréphtalate d'éthylène), de Nylon, de polyoléfines et de leurs copolymères.

FIG. 1

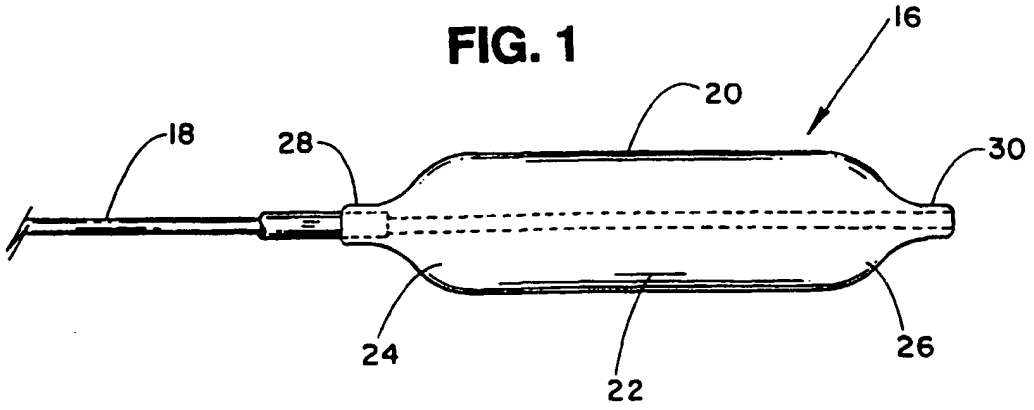


FIG. 2

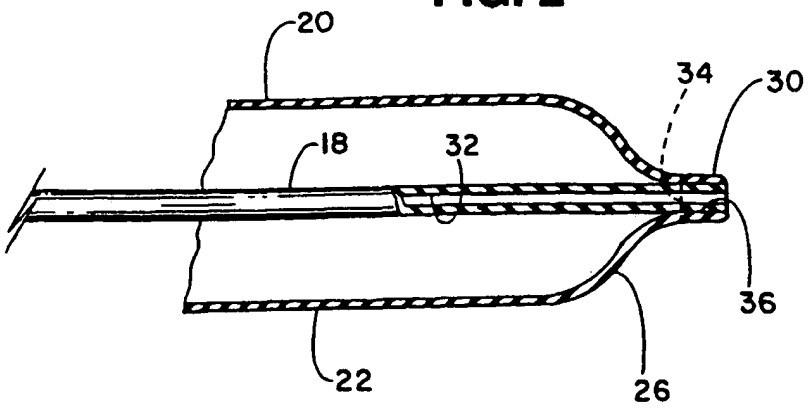


FIG. 3

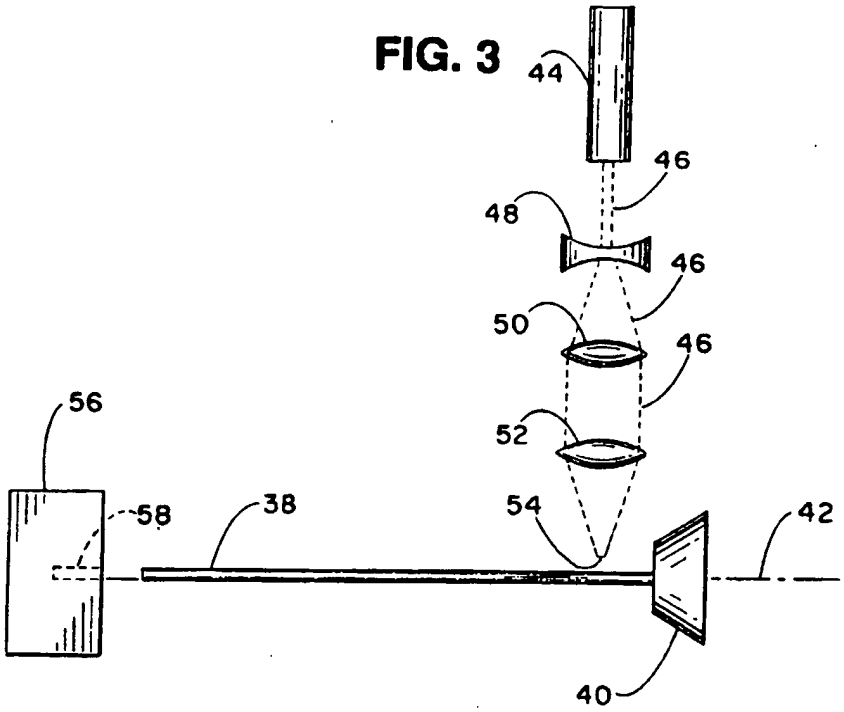


FIG. 4

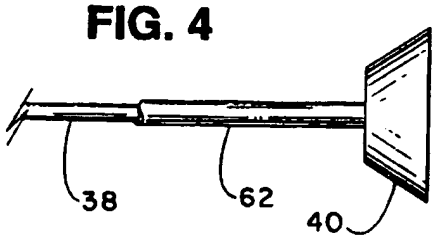


FIG. 5

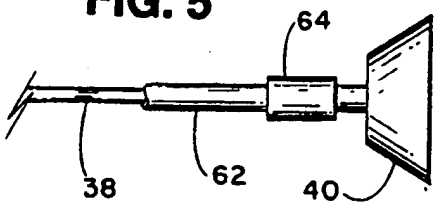


FIG. 6

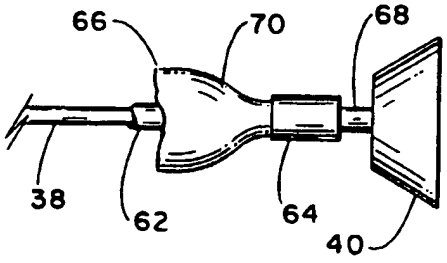


FIG. 7

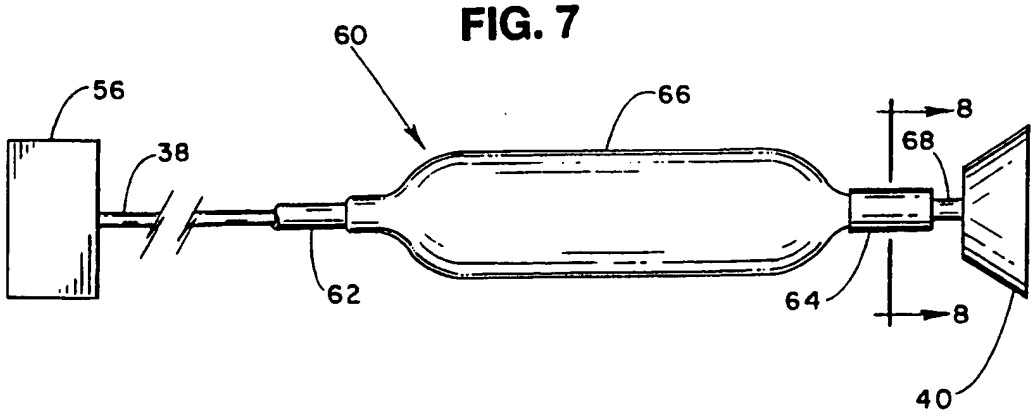


FIG. 8

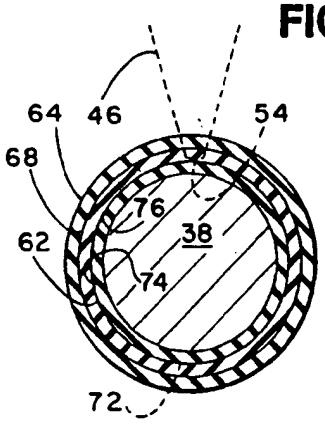
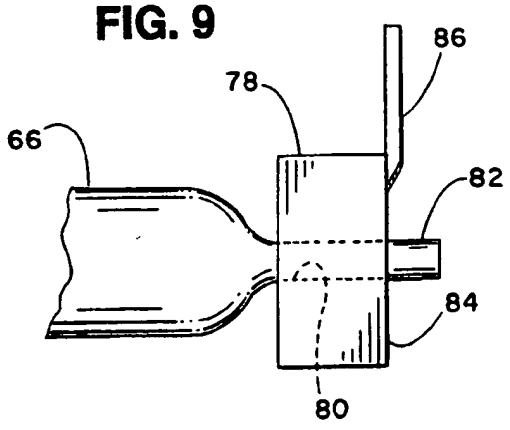


FIG. 9



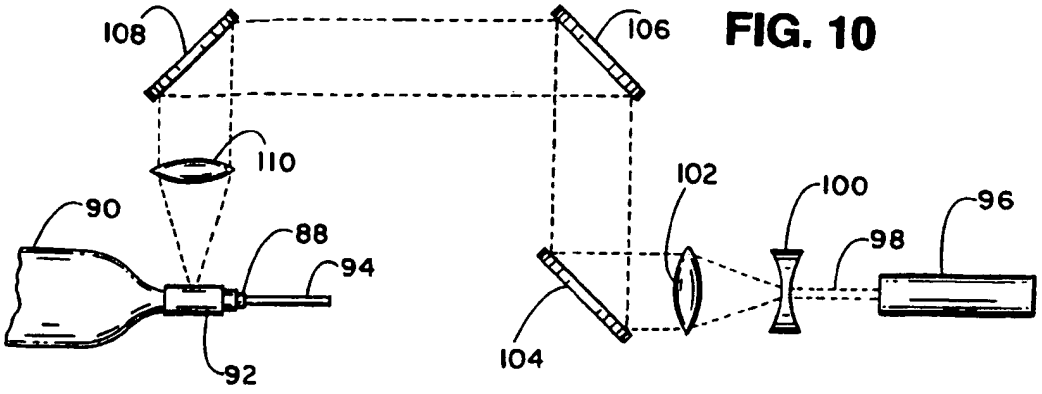


FIG. 10

FIG. 11

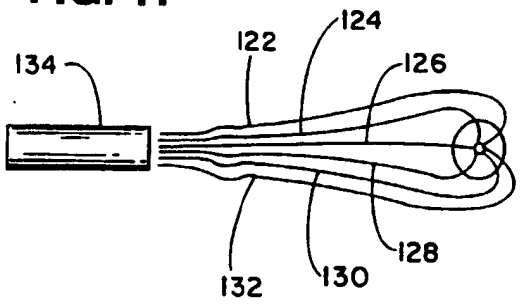


FIG. 12

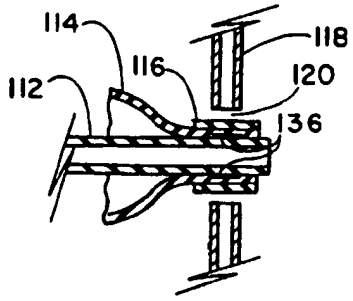


FIG. 13

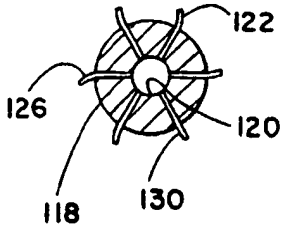


FIG. 14